IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9078

Bartle, J. May 30, 2013

Dana R. Dancer ("Mr. Dancer" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2012, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated November 13, 2002, Dr. Muttreja attested in Part II of claimant's Green Form that Mr. Dancer had severe aortic regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™, and ventricular fibrillation or sustained tachycardia which resulted in hemodynamic compromise.[3]

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Muttreja also attested that claimant had an abnormal left atrial dimension. This condition is not at issue in this claim.

Based on such findings, claimant would be entitled to Matrix B-1,[4] Level V[5] benefits in the amount of $271,456.[6]

In March, 2012, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for Dr. Muttreja's finding that claimant suffered from ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise. Dr. Gillespie explained, "[Ventricular fibrillation] occurred intraoperatively which would not meet criteria. This occurred during manipulation of the heart/aorta."[7]

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4. Claimant concedes his claim is payable, if at all, on Matrix B-1 because his Diet Drug use is less than sixty-one days. See Settlement Agreement § IV.B.2.d.(2)(b).

5. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level III benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Id. § IV.B.2.c.(3)(a). The Trust does not contest that Mr. Dancer is entitled to Level III benefits.

6. Mr. Dancer previously was paid benefits in the amount of $180,170 based on his Category One Claim. Thus, if Mr. Dancer's supplemental claim for Matrix B-1, Level V benefits is payable, he only will receive $91,286, the incremental amount by which his Matrix payment exceeds the payment he previously received. See Settlement Agreement § IV.C.3.

7. The Trust submitted the claim for review by the Consensus Expert Panel ("CEP") pursuant to Pretrial Order ("PTO") No. 6100 (Mar. 31, 2006). The CEP reviewed the claim and found: "Group affirms audit findings. Ventricular fibrillation occurring

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Based on Dr. Gillespie's finding, the Trust issued a post-audit determination denying Mr. Dancer's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, Mr. Dancer argued that there was a reasonable medical basis for his claim because the auditing cardiologist admitted that ventricular fibrillation occurred. Claimant, relying on a declaration of Robert L. Rosenthal, M.D. and a number of articles, also asserted that the Settlement Agreement does not support the Trust's contention that ventricular fibrillation must occur spontaneously. In addition, claimant contended that intraoperative ventricular fibrillation is neither induced nor benign. Finally, Mr. Dancer argued that his ventricular fibrillation occurred after removal of the aortic cross clamp and not during manipulation of his heart or aorta.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Gillespie submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting

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7. (...continued)
during separation from cardiopulmonary bypass is a frequent event, rather than indicating increased medical severity as spontaneous ventricular fibrillation does."

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Dancer's claim.

physician's finding that Mr. Dancer suffered from ventricular fibrillation or ventricular tachycardia which resulted in hemodynamic compromise. Specifically, Dr. Gillespie stated, in relevant part, that:

> 10. Based upon my review, I affirm my finding that there is no reasonable medical basis for the Attesting Physician's affirmative answer to Question L.5 of the Green Form. In reaching this conclusion I considered the recommendations provided by the Consensus Expert Panel (the "CEP") concerning Section IV.B.2.c(5)(d) of the Settlement Agreement, in light of the medical documentation submitted with this claim. A copy of the CEP recommendations is attached as Exhibit B to this Declaration.
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> 11. At Contest, I reviewed Dr. Rosenthal's excellent review of the literature concerning reperfusion ventricular fibrillation. I agree that reperfusion ventricular fibrillation has the potential to cause harmful effects and is not desirable. At no point did I contend that ventricular fibrillation in this setting is benign. Rather, it is an expected event when separating from the bypass pump immediately after surgery and not a separate 'worsened condition.' Indeed, none of the medical records submitted in this claim document any spontaneous ventricular fibrillation after that induced by separation from the bypass pump.. [sic]
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> 12. The very articles that Dr. Rosenthal cited substantiate a very high incidence of ventricular fibrillation <u>in the immediate time frame</u> after reperfusion after cardiac surgery. In the article labeled Exhibit B, an incidence rate of "reperfusion-induced ventricular fibrillation (RVF) in 60% to 100%" in all cases after aortic unclamping during cardiopulmonary bypass. Furthermore, it

is suggested that RVF is caused by oxygen free radicals and ionic disturbances involving sodium and calcium ions. The article labeled as Exhibit C quotes an incidence of RVF to be 74% to 96%. Exhibit D quotes an RVF incident of 45% to 100%. Exhibit F noted that only 13 out of 99 patients did not develop [ventricular fibrillation] in the immediate post op[erative] period, again showing the very high incident of [ventricular fibrillation] after reperfusion.

13. In conclusion, while [ventricular fibrillation] may have deleterious effects on the heart, it is an expected event incidental to cardiac surgery. Even in patients with normal to near normal cardiac function with no evidence of myocardial scar or preexisting arrhythmia, the incidence of [ventricular fibrillation] is very high as noted in Lake et. al. (Dr. Rosenthal's Exhibit F). This study excluded all patients with "history of arrhythmias or need for antiarrhythmic drugs, congestive heart failure, or ejection fraction less that 50%." Even in this low risk group, 87% of patients required defibrillation after reperfusion. This event does not indicate increased medical severity, as spontaneous ventricular fibrillation does. The medical documentation submitted in support of this Claim does not support [ventricular fibrillation] occurring beyond the immediate time frame after reperfusion.

The Trust then issued a final post-audit determination, again denying Mr. Dancer's supplemental claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an

Order to show cause why Mr. Dancer's claim should be paid. On February 25, 2013, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9005 (Feb. 25, 2013).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 30, 2013, and claimant submitted a sur-reply on May 16, 2013. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for the attesting physician's finding that he suffered ventricular fibrillation or ventricular tachycardia which resulted in hemodynamic compromise. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, claimant argues that the Trust did not properly apply the reasonable medical basis standard

because it denied his claim based on the subjective opinion of the auditing cardiologist. In addition, Mr. Dancer argues that the Trust improperly imposed causation, frequency, severity, and spontaneity requirements on him. Finally, claimant disputes that ventricular fibrillation during surgery is a benign event.

In response, the Trust argues that claimant failed to establish a reasonable medical basis for Dr. Muttreja's representation that claimant suffered ventricular fibrillation or ventricular tachycardia which resulted in hemodynamic compromise. According to the Trust, "[v]entricular fibrillation during separation from cardiopulmonary bypass is a frequent event, rather than indicating increased medical severity as spontaneous ventricular fibrillation does."

After reviewing the entire Show Cause Record, we find claimant has established a reasonable medical basis for his claim. As stated previously, a claimant is entitled to Level V benefits if "[t]he individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." Settlement Agreement § IV.B.2.c.(5)(d). The Trust concedes that claimant qualifies for payment at Matrix Level III and suffered from ventricular fibrillation. According to the Trust, however, the ventricular fibrillation Mr. Dancer experienced does not support a claim for Level V benefits because "[v]entricular fibrillation during separation from cardiopulmonary bypass is a frequent event,

rather than indicating increased medical severity as spontaneous ventricular fibrillation does." We disagree.

We previously have rejected the Trust's argument that ventricular fibrillation must occur spontaneously to be compensable under the Settlement Agreement. Specifically, in PTO No. 8624, we held that the Trust's argument that claimant was not entitled to Level V benefits because the ventricular fibrillation she experienced was "not spontaneous, but rather 'was induced by manipulation of the heart ... during surgery'" improperly required proof of causation. Mem. in Supp. of PTO No. 8624, at 17-18 (Mar. 9, 2011).

The same result is warranted here, as the Trust essentially is arguing that claimant's ventricular fibrillation occurred as a result of his aortic valve replacement surgery rather than spontaneously.[9] Such a requirement is inconsistent with the Settlement Agreement. As we have stated, causation generally is not at issue in resolving claims for Matrix Benefits. Rather, claimant must show that he or she meets the objective requirements set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only

9. In fact, Dr. Gillespie specifically explained that the ventricular fibrillation Mr. Dancer experienced was not compensable because it "occurred during manipulation of the heart/aorta," the very standard we rejected in PTO No. 8624.

> prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred ....

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97.

Section IV.B.2.c.(5)(d) of the Settlement Agreement does not require any proof that the Diet Drug Recipient suffered from ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise that was caused by Diet Drug use. We must apply the Settlement Agreement as written. Accordingly, the Trust's assertion that ventricular fibrillation experienced during separation from cardiopulmonary bypass does not satisfy the requirements of Section IV.B.2.c.(5)(d) of the Settlement Agreement is misplaced.

For the foregoing reasons, we conclude that claimant has met his burden of proving that there is a reasonable medical basis for finding that he had ventricular fibrillation or ventricular tachycardia which resulted in hemodynamic compromise. Therefore, we will reverse the Trust's denial of Mr. Dancer's claim for Matrix B-1, Level V benefits.